



PURGED 2710

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

September 21, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 51

Diane C. Hansgen, DVM
President
Fairfax Veterinary Clinic, Ltd.
11 NW First Street, P.O. Box 532
Fairfax, Minnesota 55332

Dear Dr. Hansgen:

An investigation of your veterinary medical practice at Fairfax, MN, on June 14, 2000, by the Food and Drug Administration revealed a serious deviation of Extralabel Drug Use In Animals [Title 21, Code of Federal Regulations, Part 530 (21 CFR 530)]. This deviation causes the drug prescribed by you to be adulterated within the meaning of Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act).

The extra label use of fluoroquinolones and glycopeptides was prohibited in food-producing animals in the Federal Register, (62 Federal Register 27944-27947, copy enclosed). This has been codified at 21 CFR 530.41(a)(10) and was effective August 20, 1997. Since that time you have prescribed W brand of enrofloxacin, a fluoroquinolone, for the treatment of young swine M times. This is a prohibited extra label use of the drug and causes the drug to be adulterated.

We request that you take prompt action to ensure you do not cause the adulteration of veterinary drugs used in your practice. Causing the adulteration of drugs after interstate commerce is a violation of Section 301(k) of the Act.

The above is not intended to be an all-inclusive list of violations. As a licensed veterinarian, you are responsible for ensuring that all drugs you prescribe are not adulterated and that all requirements of Act are met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

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Diane C. Hansgen, DVM
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You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Compliance Officer Robert P. Snell at the address indicated on the letterhead.

Sincerely,



James A. Rahto
Director
Minneapolis District

jeh
RPS/ccl

xc: Roland C. Olson, DVM
Executive Director
Minnesota Board of Veterinary Medicine
2829 University Avenue SE, #540
Minneapolis, MN 55414